

REMARKS

Claims 19-32, 34 and 36-50 are all the claims pending in the application. Support for new claims 46-50 can be found, for example, on page 8, lines 23-46 of the present specification.

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 to demonstrate the difference between the present invention and USP 4,613, 500 (Suzuki), and to show that the present invention provides unexpectedly superior results.

The following method for preparing a composition comprising insulin as a drug, polyacrylic acid as a water- absorbing and water-soluble base material and crystalline cellulose as a water-absorbing and water-insoluble base material is disclosed in Suzuki. See col. 7, lines 28-45.

Firstly, polyacrylic acid was dissolved in an aqueous solution of insulin. Secondly, the solution was then freeze-dried to give a powdery composition. Then, the obtained powdery composition and microcrystalline cellulose were put in a mortar and mixed thoroughly to obtain a powdery composition.

Since the drug and water-absorbing and water-soluble base material are mixed together prior to the addition of the water-absorbing and water-insoluble base material, the drug is dispersed more on or in the water-absorbing and water-soluble base material.

In contrast, in the present invention, the drug is dispersed more on or in the water-absorbing and water-insoluble base material.

Therefore, Suzuki does not disclose, teach or suggest the present invention.

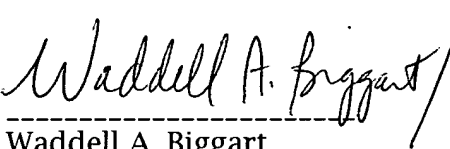
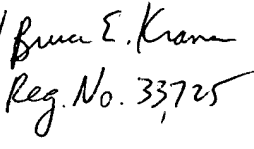
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In addition, the present invention attains high amount of drug absorption and high maximum plasma concentration (C_{max}). However, when a water-absorbing and water-soluble base material was added to the composition of Suzuki containing only a water-absorbing and water-insoluble base material, the resulting composition did not attain a higher C_{max} than the composition without the water-absorbing and water-soluble base material.

Accordingly, the present invention provides unexpectedly superior results.

Entry and consideration of this Amendment is respectfully requested.

Respectfully submitted,

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 46-50 are added as new claims.